Bureau of Radiological Health
NH Department of Health & Human Services

Radiation Safety Topics

Writing a Radiation Protection Program For A Facility With Cabinet Radiographic Or Analytical X-Ray Machines

Introduction

The New Hampshire Rules for the Control of Radiation (Rules) require each registrant to "develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of He-P 4020 through 4023." **Think of a radiation protection program as a management plan** to keep doses low and to comply with the Rules. This Radiation Safety Topics writer's guide is intended to help registrants possessing cabinet radiographic or analytical x-ray machines to write or revise their program plan. State law and the Rules establish all requirements; you will find no additional ones here. This information is not a substitute for an understanding of the requirements of the Rules as they apply to your program, but is intended to serve as an informal informational tool - a "guide for the perplexed." In what follows, a radiation protection program is referred to as an RPP.

This Radiation Safety Topics writer's guide is addressed to registrants with certain kinds of machines because there are specific rules that apply to them. Analytical x-ray machines are used for the either x-ray diffraction or x-ray fluorescence (XRF) analysis. That is, they are used for determining the microscopic structure or elemental composition of materials. Part He-P 4043 is specific to analytical x-ray machines and operations with them.

Industrial radiography is the examination of the gross structure of materials using ionizing radiation to make radiographic images. The result is what most people think of as an "x-ray." Part He-P 4034 of the Rules governs industrial radiography. Cabinet radiographic x-ray machines must meet specific requirements set out in Section He-P 4034.03. Special, simplified rules apply to them (He-P 4034.04). Registrants engaged in non-cabinet industrial radiography will have to review the requirements of the Rules, particularly those in the remainder of Part He-P 4034, for applicable requirements. It is an unfortunate coincidence that the two parts of the Rules covering industrial radiography and analytical machines (He-P 4034 and He-P 4043) may be confused by a simple interchange of the last two digits.

General points

Parts He-P 4020 through 4023 contain the basic radiation protection standards. Part He-P 4023 applies only to possessors of radioactive material, so users of x-ray machines only can ignore it. On the other hand, x-ray machine registrants have to consider the requirements of

other portions of the Rules as well. It is reasonable to address the requirements of these other rules in your RPP as you work on it. Appendix A of this document lists portions of the Rules that you should become familiar with, if you are not already.

In addition to the various annual dose limits, it is a key radiation safety practice and requirement (He-P 4020.04(b)) to keep exposures to radiation "as low as reasonably achievable" (ALARA). This may be done using procedures (e.g., operating and other procedures and worker instruction) and engineering controls (e.g., shielding) based upon sound radiation protection principles. You may take economic and social factors into account in deciding what is reasonable.

Not all of the following points may be applicable to your facility and operations. If this is the case, you do not need to address them in your RPP. On the other hand, some registrants may need to include far more detailed information than is suggested by this document. Therefore, you should review your particular activities and the applicable requirements of the Rules in order to assure your compliance with them. If you conclude that a requirement does not apply to your situation, you might say so in your RPP, with a brief explanation as to why it is not applicable. This will indicate that you have considered the point.

The components of your RPP do not have to be in a stand-alone document. For instance, if you have an OSHA compliance manual, you can build your RPP into it. However, all components of your RPP should be identifiable as such. The Bureau of Radiological Health will expect you to be able to identify and explain the components of your program during any inspection. (Note: Records of the provisions of your RPP must be maintained until you terminate your registration. Records of annual reviews of your RPP and how well it is working are to be maintained for at least 3 years.)

If you do not have a copy of the New Hampshire Rules for the Control of Radiation, we can provide one to you for $10. This charge is to recover the costs of printing and mailing. It is not necessary to obtain the Rules directly from us, but you must have certain parts available (see section F below). If you wish to obtain a copy of the Rules from this agency, request a copy of the Rules and indicate a return address. Payment should accompany the order. We ask that checks or money orders be made payable to: **Treasurer - State of New Hampshire**., Send your order to:

New Hampshire Bureau of Radiological Health
6 Hazen Drive
Concord, NH 03301-6527.

Alternatively, we can provide you with the Rules in WordPerfect 5.1 or MS Word format on a PC-compatible floppy disk by asking for them and providing a return address. Note that Parts He-P 4020 through 4022 will have to be available to your workers in printed form.

If you have any questions about compliance with the Rules, registration requirements for x-ray machines, radiation safety, or related points, please call us at 603-271-4588, or write to us at the address above. You can E-mail us at nhbrh@dhhs.state.nh.us. We will try to help. Comments about this Radiation Safety Topics and suggestions for improvements are welcome.

Contents of a Radiation Protection Program

Some items that are appropriate (and possibly required) parts of an RPP are:

A. Goal of the RPP, authority, and access to information.

The goal of a radiation protection program is to keep radiation exposures to workers and the general public to levels as low as reasonably achievable (ALARA).

Your RPP might specify:

1. who is delegated the tasks of developing and promulgating procedures and who is responsible for ensuring they are followed.;
2. where the procedures, equipment manuals, and records are kept; and
3. the fact that these materials may be reviewed at any reasonable time.

A registrant is ultimately responsible for safety, but you may delegate the job to someone.

B. Operating procedures.

He-P 4019.03(b) requires, among other things, that "the operating procedures applicable to activities under the registration" be posted or otherwise be available to workers. For cabinet radiography there is a provision (in subparagraph He-P 4034.04(a)(1)) requiring that workers receive written operating procedures and be instructed in them. Paragraphs (a) and (b) of Section He-P 4043.06 require written operating procedures for operators of analytical x-ray equipment and specify their minimum content. Your RPP might identify what written procedures are available. See section F, "Posting and labeling," about the requirements for posting or otherwise making procedures available to workers.

Written procedures for cabinet radiography might address such topics as:

a. basic operating procedures;
b. how to conduct and record the results of tests for the proper operation of interlocks;
c. any necessary equipment maintenance, how to do it, and who is allowed to do it; and
d. who is to carry out the training and evaluation of workers and how.

For analytical systems, the RPP should include at least the topics set out in Sections He-P 4043.06 and 4043.07 including how dosimetry is to be worn and controlled, if it is provided.

C. Personnel monitoring (e.g., film or thermoluminescent dosimeter (TLD) badges).

Applicable occupational dose limits are given in Sections He-P 4020.05, 4020.11, and 4020.12. Generally, registrants are required to supply and require the use of individual monitoring devices for the purpose of monitoring occupational exposure to those individuals (adults, minors, and declared pregnant women) likely to receive in one year, from external sources, doses exceeding 10% of any applicable limit (He-P 4022.02(b)). It is also necessary to monitor occupational exposure when required by a specific provision to do so, as in paragraphs (b) and (c) of Section He-P 4043.07.

The doses actually received will depend on a combination of factors such as the distances involved, the composition of any barrier (shielding) between the individual and the x-ray source, the technique factors (x-ray tube potential and current) used, and the number of exposures made

over the course of a year. If you have previous dosimetry results, survey measurements, or calculations, they can help you to decide whether you need to provide monitoring devices to your workers.

It should be noted that operators of cabinet radiographic x-ray machines should receive negligible doses when operating certified or certifiable cabinet machines. Personnel monitoring (e.g., film badges) will not be required by the Rules. Operators of analytical machines may be expected to receive some extremity dose in certain situations. These situations need to be evaluated in terms of whether the operator is likely to exceed 10 % of the allowable annual limit. See also paragraphs He-P 4043.07(b) and (c).

Your RPP might state whether or not you will provide personnel monitoring devices to your workers. It is reasonable to state the basis for your decision as a guide for your annual reviews. If you intend to provide badges, there should be:

1. a procedure, or general instructions to employees as to the location on the body to wear the badge (most typically on the trunk of the body, toward the source of radiation, or on the finger or wrist for extremity monitoring; see Section He-P 4022.03);
2. someone designated by name or title to be in charge of the badges;
3. a location for the control badge where it will not be exposed to radiation from your activities involving ionizing radiation;
4. a statement of badge exchange frequency and how the exchange is to be accomplished;
5. information on how employees are to learn what their total annual dose is (He-P 4019.05).

If you are not required to monitor doses to workers, nothing prevents you from providing personnel dosimetry services to them. Registrants often do so voluntarily for personnel relations purposes or for potential liability reasons. Any dosimetry service you employ should meet the requirements of He-P 4022.01(c), and commercial dosimetry services should be able to demonstrate this to you. We can direct you to a list of dosimetry service providers.

He-P 4003.01(ah) defines a "declared pregnant woman." This definition is important and is used in Section He-P 4020.12. It requires you to maintain the dose to an embryo/fetus from occupational exposure to a declared pregnant woman below 500 millirem for the duration of the pregnancy, and to avoid substantial variation in exposure rate from month to month during that time. If there are any women working under your registration, you should become familiar with both of these sections of the Rules insofar as the definition of a “declared pregnant woman” has implications that relate to a woman’s choice to declare her pregnancy or not, and whether the dose limits of He-P 4020.05 or He-P 4020.12 must be applied. It is also necessary to evaluate the monitoring requirements of He-P 4022.02(b) with regard to calculating 10% of the lower applicable limit of He-P 4020.12.

In many industrial radiographic and analytical applications where personnel dosimeters have been used, annual exposures have been found to be well below 500 millirem, and often below the minimum quantifiable dose measured with film badges and TLDs. This may make application of this section of the Rules of no practical concern. Nevertheless, **all women in your employ should be made aware of these provisions of the Rules**.

D. Quality assurance (QA) programs.

Your RPP should list any quality assurance programs you have, even if only to specify adherence to an industry standard. For instance, do you have an annual, biennial, or other cycle for x-ray machine preventive maintenance? Is a film processing QA program in place? At this time, no maintenance cycle or QA program is required by the Rules, however, it is suggested that you have one containing detailed written procedures which can be referred to. Either the RPP or the procedures should give:

1. the QA procedures;
2. the intervals at which the QA steps are carried out;
3. the actions to take if discrepancies are noted; and
4. the individuals responsible for carrying out the programs.

E. Worker instruction.

In addition to any schooling or previous experience your workers may have, the Rules require each registrant to instruct workers in **site-specific facts, policies, and procedures relating to radiation safety**. Training is appropriate for each new hire and at least annually thereafter.

Your RPP might state who is responsible for providing training or seeing that it is done.

Training must include (He-P 4019.04):

1. that there is a source of radiation present and that its operation may pose some (typically small) risk to the operator and perhaps others;
2. instructions:
   a. in the risks inherent in the use of radiation, both to the worker and potential offspring;
   b. in precautions and procedures to minimize exposure to radiation; and
   c. about the purposes and functions of protective devices used (e.g., audible and visual indicators, interlocks, labels, shutters, etc.);
3. that employees are to comply with all applicable sections of the Rules and your specific policies and procedures for radiation safety;
4. that employees have a responsibility to report promptly to you, or an individual identified by name or title, anything which may lead to unnecessary exposure or which is, or may lead to, a violation of the Rules or of your policies and procedures;
5. notice of any radiation exposure reports due them under He-P 4019.05.

There are also specific topics for instruction set out in Section He-P 4034.04 for cabinet radiography and in Sections 4043.06 and 4043.07 for operators of analytical x-ray machines.

Your instruction should also include the definitions of terms used in the Rules (e.g., "declared pregnant woman," "dose," etc.) and the various applicable dose limits in He-P 4020 (e.g., embryo/fetal dose, eye dose, extremity dose). The extent of instruction must be commensurate with the risks involved.

It is important to document the training you provide. The documentation might well be a simple statement of the date of the training, the topics covered, the trainer's name, and names of those trained.

F. Posting and labeling.

He-P 4019.03 contains posting requirements for all registrants. Because they are part of the Rules, you need not specifically incorporate them into your RPP. However, you may wish to identify where Form 5, "Notice to Employees" and the other documents are to be posted, and who is responsible for maintaining postings and labeling.

Review He-P 4019.03(b) on posting requirements, and note that He-P 4019.03(c) allows you to post a notice describing certain items, and where they may be examined, in lieu of posting the items themselves. Form 5, "Notice to Employees," must be posted. Form 5 and the other items, must appear in places where they will be easily seen (He-P 4019.03(c) and (f)). There are no specific posting requirements in Section He-P 4034.04 for cabinet radiography, but there is a posting requirement in Paragraph He-P 4043.05(e) for each room or area containing analytical equipment.

Certain labels are required by the Rules. He-P 4022.13(d) requires x-ray machines to be labeled in a conspicuous manner that radiation is produced when the equipment is energized. On newer machines, the warnings are generally put there by the manufacturer. There are specific additional labeling requirements in Section He-P 4043.05.

All postings and labels should be reviewed periodically to ensure that any that are faded, worn, damaged, or defaced are promptly repaired or replaced. We can provide you with any necessary copies of Form 5, “Notice to employees.”

G. Dose limits to the public.

The Rules contain an explicit limit on doses to members of the public (He-P 4020.13). Your RPP should address this issue.

Basically, He-P 4020.14 says you can evaluate the dose to the individual likely to receive the highest dose from your operations but who is not occupationally exposed. For instance, it might be someone in an adjacent work area or office (see He-P 4003.01(ci), "occupational dose"). If the evaluation indicates that individual will not receive a dose exceeding the annual limit of 100 millirem (or if present continually will not receive more than 2 millirem in any one hour, nor more than 50 millirem annually), then you are in compliance.

You may reason in your RPP from creditable data (e.g., area badge data, survey measurements, manufacturer's information, shielding evaluations, or physical principles) that your operations are in compliance with the Rules. For instance, suppose you have evidence that occupationally exposed individuals receive annual doses of 100 millirem or less, which is likely to be the case, particularly for cabinet radiographic machines. Assume the maximally exposed member of the public is farther away from the x-ray source than the worker and there is a wall between her and the x-ray source. It would generally follow from the physics of the situation that the individual's exposure would be less than the applicable limit on doses to individual members of the public.

H. Annual RPP reviews.

Your RPP may contain information:

1. saying who is responsible for carrying out the reviews;
2. at what intervals the reviews are to occur, if more frequently than annually; and
3. giving any procedures for conducting the reviews and recording the results.

You must review your RPP, and document the review, at an interval not to exceed one year (He-P 4020.04(c)). Items such as how well your RPP is working; if it can it be made better; simpler; and noting any circumstances that have significantly changed (e.g., additional activities, increased use of machines, additional training needs identified, lessons learned, etc.) are appropriate inclusions.

I. Recordkeeping.

Part He-P 4021 covers recordkeeping. Your RPP might identify

1. the records to be kept;
2. who is responsible for maintaining records; and
3. where they are kept.

Appendix A. Some applicable portions of the New Hampshire Rules for the Control of Radiation for activities that involve the use of cabinet radiographic or analytical x-ray machines.

This list is intended to highlight some parts or sections of the Rules you may wish to become familiar with. Some may be more applicable to you than others, but you should at least be aware of the existence and general import of most of them. The omission of any part or section of the Rules from the list below does not mean that it does not apply to your facility, machines, operations, personnel, practices, etc. Compliance with all applicable portions of the Rules is a registrant's responsibility.

Part/Section	Comment
He-P 4001	Scope, exemptions, and provisions: applies to all registrants.
4001.03	Records.
4001.04	Inspections.
4001.05	Tests: He-P 4001.05(a) applies.
4001.07	Communications.
4001.08	Units of exposure and dose.
He-P 4003	Definitions.
He-P 4019	Notices, instructions, and reports to workers; inspections.
4019.03(b)	Postings required.
4019.03(c)	Provision to post a notice describing documents and where they may be examined, if they are not posted pursuant to He-P 4019.03(b).
4019.03(d)	Form 5, "Notice to employees" to be posted.
4019.03(e) through (g)	When and where postings are to appear.
4019.04	Instructions to workers.
4019.05	Notifications and reports.
4019.06 through 4019.09	Inspections.
He-P 4020	Standards for protection against radiation. (Note: Sections He-P 4020.06 through 4020.08 deal with internal exposure due to intakes of radioactive material, and typically do not apply to radiation machine registrants.)
4020.04	Radiation protection programs.
4020.05	Occupational dose limits for adults.
4020.09	Prior occupational dose.
4020.10	Planned special exposures. No x-ray machine registrant is expected to use this section. It is for operations involving otherwise unavoidable dose from radioactive material.
4020.11	Occupational dose limits for minors.
4020.12	Dose to an embryo/fetus.

4020.13	Dose limits to members of the public.
4020.13	Compliance with dose limits to the general public.
He-P 4021	Records, reports, and additional requirements. (Note: Parts He-P 4021.04, 4021.06, 4021.09, 4021.10, 4021.15, 4021.19, 4021.20 and 4021.21 typically do not apply to radiation machine programs.)
4021.02	Records of radiation protection programs.
4021.03	Records of surveys.
4021.05	Records of prior occupational dose.
4021.07	Records of individual monitoring (e.g., film badge, TLD) results.
4021.08	Records of doses to members of the public. This will probably include your initial, and subsequent, evaluations (including any measurements) of radiation doses to the public.
4021.11	Form of records.
4021.12	Reports of lost, stolen, or missing machines.
4021.13	Notification of incidents.
4021.18	Notifications and reports to individuals.
He-P 4022	Surveys and monitoring. (Note: Sections He-P 4022.03, 4022.06, 4022.07, 4022.08, 4022.15, and 4022.16 typically do not apply to radiation machines.)
4022.01	General. This section contains the general requirement to make surveys of radiation levels and hazards. Note the definition of "survey" in He-P 4003.01(eh).
4022.02	Conditions requiring individual monitoring of occupational dose. This section contains the "10 % rule" for whether personnel monitoring (e.g., film badges) is required. There are specific requirements in Section He-P 4043.07.
4022.03	Location of individual monitoring devices (e.g., film badges).
4022.04	Control of access to high radiation areas. This section and the next may apply to larger cabinet radiographic machines.
4022.05	Control of access to very high radiation areas.
4022.09	Security of stored sources of radiation.
4022.10	Control of sources of radiation not in storage.
4022.11	Caution signs. Describes the radiation symbol and makes some other provisions.
4022.12	Posting requirements. You will have to determine whether these provisions apply to your facility and operations. There may be cabinet radiographic machines that require signs.
4022.13	Exceptions to posting requirements. These probably do not apply.
4022.14	Labeling. See paragraph (d).
He-P 4034	Industrial radiography.
4034.03	Definitions. Note particularly paragraphs (d) through (g). These are crucial for determining whether you have a cabinet radiographic x-ray machine and, therefore, whether you are eligible for the exemptions of Section He-P 4034.04.

4034.04	Exemptions. Here are the reduced requirements applicable to certified and certifiable cabinet radiographic machines.
He-P 4040	Registration of radiation machine facilities. (Note: Sections He-P 4040.06, 4040.09, and 4040.10 typically do not apply.)
4040.04	Shielding plan review. All new and modified facilities must have a review done of their shielding requirements. By definition, cabinet radiographic machines are self-shielded units when operating in the way designed. The shielding evaluation should say this. The review for analytical machines may, or may not, be as simple. Some evaluation will be necessary.
4040.05	Registration of radiation machines. All x-ray machines are to be registered, whether in use or not.
4040.07	Expiration of registration.
4040.08	Renewal of registration.
4040.11	Radiation machines in storage. Any radiation machine may be registered as "in storage" at the beginning of the "registration year" if it meets certain conditions set out in this section.
He-P 4043	Analytical x-ray equipment.
4043.03	Definitions.
4043.04	Equipment requirements.
4043.05	Area requirements.
4043.06	Operating requirements.
4043.07	Personnel requirements.
He-P 4070	Fees.
4070.01	Purpose and scope.
4070.02	Payment of fees.
4070.03	Method of payment.
4070.05	Schedule of fees for registration of radiation machines.
4070.06	Proration of fees. Fees are prorated on a quarterly basis with the "registration year beginning August 1 of each calendar year. The proration is based on the date the machine is acquired.

Appendix B. Federal requirements for cabinet radiographic x-ray machines.

The US Food and Drug Administration (FDA) has jurisdiction over the manufacture, marketing, sales, and installation of x-ray machines. New Hampshire's Rules apply to their use. The federal requirements for cabinet x-ray systems are in Title 21 of the Code of Federal Regulations, Section 1020.40 (21 CFR 1020.40), which appears below. The exemptions in Section He-P 4034.04 of the New Hampshire Rules for the Control of Radiation apply to "certified" or "certifiable" cabinet x-ray machines. Essentially, an x-ray machine is a certified machine when it has been designed and built to meet the compliance standard promulgated by FDA in 21 CFR 1020.40 and the manufacturer has certified to the FDA that the machine meets the standards.

A cabinet radiographic x-ray machine does not have to be a "cabinet" in the usual sense of the word. Baggage inspection and similar machines also fall into this category. It may even be a room large enough for individuals to walk into. If it is such a room, 21 CFR 1020.40 puts additional requirements on the unit beyond those for a machine with a much more limited volume and accessibility. Any cabinet radiographic x-ray machine manufactured on or after about April 1975 should be a certified machine. It should have a label somewhere attesting to that fact.

Older cabinet-style machines may also meet the standard, although that will have to be determined on a case-by-case basis. Some people have constructed their own cabinet machines. Under our older rules they were acceptable. They may still be acceptable if they meet, or can be brought to meet, the federal standard. Any non-certified cabinet-style machine meeting the 21 CFR 1020.40 standard, whether it does so as it stands or if upgraded to do so, is a "certifiable" cabinet machine under the New Hampshire Rules for the Control of Radiation. The Bureau of Radiological Health has been told that the owner of a cabinet-style machine may upgrade it for the owner's own use without running afoul of FDA's requirements on manufacturers.

If you have a machine you wish to have accepted as certifiable by this Bureau, please let us know. We will work with you to try to achieve it. If your machine is not a certified or certifiable unit, then you are engaged in non-cabinet industrial radiography and the full rigor of Part He-P 4034 applies.

21 CFR 1020.40 Cabinet x-ray systems.

(a) Applicability. The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x- ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.

(b) Definitions. As used in this section the following definitions apply:

(1) Access panel means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) Aperture means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x-radiation.

(3) Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) Door means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) Exposure means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(6) External surface means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) Floor means the underside external surface of the cabinet.

(8) Ground fault means an accidental electrical grounding of an electrical conductor.

(9) Port means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) Primary beam means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) Safety interlock means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) X-ray system means an assemblage of components for the controlled generation of x-rays.

(13) X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) Requirements--
  (1) Emission limit.
    (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.
    (ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross- sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.
  (2) Floors. A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.
  (3) Ports and apertures.
    (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.
    (ii) The insertion of any part of the human body through any aperture shall not be possible.
  (4) Safety interlocks.
    (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.
    (ii) Each access panel shall have at least one safety interlock.
    (iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.
    (iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.
  (5) Ground fault. A ground fault shall not result in the generation of x-rays.
  (6) Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable there shall be provided:
    (i) A key-actuated control to insure that x-ray generation is not possible with the key removed.
    (ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.
    (iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray

system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled ``X-RAY ON''.

(iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled ``X-RAY ON''.

(7) Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the ``on'' position.

(8) Warning labels.

(i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

Caution: X-Rays Produced When Energized

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

Caution: Do Not Insert Any Part of the Body
When System is Energized--X-ray Hazard

(9) Instructions.
  (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x- ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.
  (ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10)(i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.
  (i) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.
  (ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(d) Modification of a certified system. The modification of a cabinet x-ray system, previously certified pursuant to Sec. 1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of Secs. 1010.2 and 1010.3 of this chapter.